UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,287	07/16/2001	John A. Montgomery	1381/00067	2444

7590 12/08/2004

Burton A Americk
Connolly Bove Lodge & Hutz
PO Box 19088
Washington, DC 20036-0088

EXAMINER	
KHARE, DEVESH	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,287	MONTGOMERY ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 24-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's remarks filed on 08/19/04 are acknowledged.

The examiner withdraws the prior art reference Chou et al. (U.S.Patent 5,821,357) applied in the 35 U.S.C. 103(a) rejections of the Final Office action dated 05/19/2004 in response to applicant's remarks that Chou et al. does not suggest a reaction of a purine nucleoside having a 6-alkoxy group to obtain the desired final product.

The finality of the Office Action mailed on 05/19/2004 has been withdrawn.

Claims 21-23 and 38-43 have been cancelled. Claims 20 and 30 have been amended.

Claims 43-48 have been withdrawn from consideration as being drawn to non-elected subject matter.

Claims 1-20 and 24-37 are currently pending in this application.

During the course of reconsideration of the application, a prior art reference not previously disclosed by the applicants or the examiner came to light (see rejection below).

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-20 and 24-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (U.S. Patent 4,751,221).

The claims 1-20 and 24-37 are directed to methods of synthesizing 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine, which are defined as:

(1) Claims 1-19 are directed to a method of synthesis of 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine. The synthesis includes the steps of first reacting the anionic form of 2-chloro-6-substituted purine with a protected 2-deoxy-2-fluoro-D-arabinofuranose, then reacting the product with an alkoxide to provide 2-chloro-6-alkoxy purine nucleoside and finally, reacting the 2-chloro-6-alkoxy purine nucleoside with ammonia to yield the 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine;

(2) Claims 20 and 24-37 are directed to a method of synthesis of 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine. The synthesis includes the steps of first reacting the anionic form of 2-chloro-6-amino purine with a protected 2-deoxy-2-fluoro-D-arabinofuranose, then reacting the product with ammonia to yield the 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine;

Dependent claim limitations set forth in dependent claims include the 6-substituted group in purine is a halogen, anionic form is an alkali metal salt or organic amine salt such as DBU; 3- and 5- hydroxyls of the arabinofuranose is selected from the group consisting of acyl group, ether group, and combinations thereof; the group at C-1 is selected from the group consisting of halo, alkylsulfonyloxy, and arylsulfonyl groups, coupling reaction solvent is selected from the group consisting of acetonitrile,

dimethylformamide or dimethylacetamide, and sodium methoxide is used as base and an alcohol is used with the base.

Watanabe et al. teach the synthesis of 2-fluoro-arabinofuranosyl purine nucleosides (abstract). The preparation of 2'deoxy-2'-fluoro-β-D-arabinofuranosyl nucleosides wherein the heavy metal derivative of a 2-halo-6-substituted-purine (III) is reacted with a protected and activated 2-deoxy-2-fluoro-D-arabinofuranose in an appropriate solvent such as acetonitrile, dimethylformamide or halogenated hydrocarbon (col. 2,lines 45 through col. 3, line 25). The use of methanolic ammonia in the saponification of the said intermediate is disclosed (col.3, lines 45-55). The 6-hydroxy-substituted nucleosides are prepared by base hydrolysis of 6-halo- nucleosides (col.4, lines 45-50). Furthermore, Watanabe et al. disclose the arabinofuranose moiety having 3- and 5- hydroxyl substituents such as acyl or aroyl group and the group at C-1 is a halo or an acetoxy and 6-alkoxy or amino substituted purine moiety (col. 2, lines 15-40).

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to select values for variables in the carbohydrate moiety and in the purine moiety in the preparation of 2-chloro-9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl)-9H-purin-6-amine from among those taught by Watanabe et al., because Watanabe et al. had disclosed that such nucleosides were useful as antiparasitic agents, especially against Leishmania tropica (Col.1, lines 10-15).

Applicant has not demonstrated any criticality or unexpected result, which stems from selection of particular values for the variable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
December 01,2004